

Prior Election Requirement and New Restriction Requirement

The application contains claims 1-99.

In response to the election requirement set forth in an office action dated June 5, 2001, Applicants elected the species of Example 22, i.e., a single, completely described compound, and identified claims 19-37 as reading on the compound and its use. Applicants also traversed the requirement to the extent it sought to have the subject matter embraced by claims 19-37 restricted in any manner on the basis that these claims embrace a single inventive concept.

Applicants' election of the species of Example 22 gave the Examiner a species with which to begin examination, and the Examiner now has provided an Office Action on the merits that also seeks to enter a restriction requirement.

The Examiner now seeks to enter a restriction requirement under 35 U.S.C. § 121 between the two Groups identified in the Office Action, based on the statement that "[t]he examiner will now use this species as a reference point to create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence."

Applicants respectfully submit that the statement upon which the restriction is based is incomprehensible and not supported in law or fact, and the restriction is impossible to implement because the members of the Groups are not found in the application and are not consonant with the election made by Applicants, even assuming that there exists a typographical error in the identification of the Groups. Further, the Examiner did not address Applicants' earlier statement regarding traverse of any restriction of the claims covering the elected species.

Applicants respectfully submit that the statement "to create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence" is incomprehensible,

both in the abstract and as applied in the Office Action. The Office Action articulates neither definitions for 'natural genus,' 'liberal interpretation,' or 'the doctrine of legal and chemical equivalence,' nor bases in law or in practice for these concepts. Further, Applicants respectfully submit that equivalence of any sort has nothing to do with genus and species relationships as they relate to restriction and election requirements. As applied in the Office Action, the statement has led to a 'natural genus' that is neither a natural creation nor a genus that encompasses the elected species.

In response to the restriction requirement, Applicants respectfully submit that it is impossible for Applicants to select a group for prosecution because the Groups are not found in the application. Obviously, therefore, the elected species does not fall into either group.

The Groups are based, *inter alia*, on Formula I wherein "t is 2" and "R1, R20 and R21, R21, and R2 are all other moieties not covered in group I." However, 't,' 'R20,' and 'R21' do not appear in Formula I. Further, the elected species is not a compound of Formula I. Also, even if there exists a typographical error and the restriction was intended to be based on Formula II (the formula set forth in claim 19), the groups make no sense because t cannot be 2 in Formula II. Thus the Groups are not found in the application.

Applicants have elected the species of Example 22, which is not a compound of Formula I. Therefore, Applicants cannot select a group that satisfies the requirement for restriction. To the extent that the Examiner intended for the species of Example 22 to fall within a group, Applicants select that group to satisfy the practice requirement that a group be selected in response to a restriction, even if the requirement is traversed.

To the extent the restriction requirement purports to restrict claims 19-37 in any way, Applicants respectfully traverse the requirement. Claims 19-37, which read on the species of Example 22 and its use, embrace but a single inventive concept.

Applicants further submit that the creation of a 'natural genus' in this matter that goes beyond claims 19-37 is both improperly arbitrary and contrary to United States Rules of Practice. Applicants' identification of claims that read on the elected species provides the claims that should be examined. These are the claims that are 'generic' to the elected species. Any claim that does not read on the elected species isn't generic to the elected species, and clearly does not belong in a 'natural genus,' whatever that is, based on the elected species.

Thus, Applicants respectfully traverse the restriction requirement of this Office Action.

Formal Rejections

Because each of the rejections goes only to part of the claims, each of the following remarks go to that part directed to the elected species and claims that are generic thereto.

Claim 33 stands rejected under 35 U.S.C. § 112, first paragraph, as not supported by a utility, and thus is said not to teach a skilled practitioner how to use the invention. Applicants respectfully traverse this rejection. "[I]nhibiting a retroviral protease" is a specific utility. As set forth in the application at pages 154-161, HIV protease is inhibited by compounds of claim 33, as illustrated by both enzyme and CEM cell assays. Further, it is well known to skilled practitioners that inhibition of retroviral protease is effective in treating a number of diseases, including HIV, respiratory syncytial, virus, hepadnavirus, and cytomegalo virus. Indeed, treatment of such diseases, and others, by inhibiting retroviral protease is disclosed in US Patent No. 5,756,533, which is incorporated by reference into the application. Therefore, Applicants

respectfully submit that a utility is described in the specification in a manner that instructs a skilled practitioner how to use the claimed invention of claim 33.

The citation in the Office Action of *In re Fouché* and *In re Wands* is unavailing. Applicants respectfully submit that the application fully provides the information required to inform a skilled practitioner how to use the invention. In particular, the application fully satisfies the *Wands* factors cited by the Examiner. Applicants respectfully submit that the predictability of inhibiting retroviral protease, which is what is claimed, is well established in the specification for compounds of claim 33 at pages 154-161. The enzyme and CEM cell assays show the effectiveness. Dosage and other treatment information are set forth at pages 163-169. Applicants respectfully submit the effectiveness of other compounds of the claims is reasonably supported by the illustrated effective inhibiting retroviral protease in the Examples. In this regard, Applicants respectfully submit that treatment of specific diseases, to which the Examiner has directed the argument relating to the *Wands* factors, is not a relevant enquiry. Applicants respectfully traverse this rejection.

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite in view of a typographical difficulty. Parts of the structural formula were printed over the text. Claim 30 has been amended to correct this problem, and Applicants respectfully submit that this amendment obviates the rejection.

Claim 34 stands rejected under 35 U.S.C. § 112, second paragraph, because the phrase "a retroviral infection" is said to be indefinite. Applicants respectfully traverse this rejection. As described above, retroviral infections are well known to skilled practitioners. The phrase is not made indefinite because a particular disease, such as AIDS, is not recited.

In claim 37, the phrase "in combination with other drugs" is said to make the claim indefinite under 35 U.S.C. § 112, second paragraph. Applicants respectfully traverse this rejection. The phrase is well defined in the claims as "drugs for the treatment of AIDS or the symptoms of AIDS." Additional information regarding and examples of such drugs are set forth at pages 167-168 of the application.

Applicants respectfully submit that claims 30, 34, and 37 are in condition for allowance.

On the Merits

Claims 19-37 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or under 35 U.S.C. § 103 as unpatentable over, Jungheim, US Patent No. 5,733,906. In particular, the compound "3-Isoquinolinecarboxamide, N-(1,1-dimethylethyl)-2-[3-[[3-[(4-fluorophenyl)sulfonyl]-2-[(methylsulfonyl)amino]-1-oxopropyl]amino]-2-[3S-[2[2S*(R*),3 α ,4e.be" said to be disclosed at columns 1-68, is said to be anticipatory. With regard to the obviousness rejection, the Office Action alleges that "Jungheim teaches the instant compounds as disclosed in Formula I wherein ..."

Applicants respectfully traverse the anticipation rejection. The compound cited from Jungheim contains a fluorophenyl moiety. However, the elected species is devoid of such a moiety. Therefore, Jungheim does not anticipate the elected species. Further, with regard to the remainder of claims 19-37, Applicants respectfully submit that Jungheim does not disclose the claimed invention. In particular, the R moiety (left end) of Jungheim requires an —N(H)— moiety between the R^o — and —C(R²) — moieties. This R^o — N(H) — C(R²) — structure simply does not exist in Formula II, and thus is not found in claims 19-37. Therefore, Applicants respectfully submit that Jungheim does not disclose the claimed invention.

Further, Jungheim does not suggest the claimed invention, and Applicants respectfully traverse this rejection. In particular, the Office Action is directed to rejection of compounds of Formula I, which is neither the elected species nor compounds of Formula II, as required in claim 19. Applicants respectfully submit that the appropriate enquiry is whether Jungheim suggests the elected species or compounds of Formula II. In view of the left end structure required by Jungheim's disclosure, Applicants respectfully submit that Jungheim does not suggest the claimed invention. There is no suggestion in Jungheim that the left end structure can be modified to yield compounds of the invention and their uses.

CONCLUSION

In response to an earlier office action, Applicants elected the species of Example 22 for examination, and identified claims 19-37 as reading on the compound of Example 22 and its use. The restriction requirement of this office action is impossible to implement because the members of the Groups are not found in the application. Also, the elected species does not fall into either group for which the restriction is sought. Further, because the subject matter embraced by claims 19-37 is a single inventive concept, Applicants respectfully traverse the restriction.

Applicants respectfully traverse the formal rejections, as the invention is described in such terms as to enable a skilled practitioner to make and use the invention, and the application particularly points out and distinctly claims the subject matter Applicants regard as the invention.

The cited art neither suggests nor discloses the claimed invention. The Examiner has applied the art to compounds of Formula I, but claims 19-37 are directed to compounds of Formula II, which is neither suggested nor disclosed in the cited art.

Therefore, Applicants respectfully submit that claims 19-37 are in condition for allowance and earnestly solicit favorable action thereon.

Respectfully submitted,

Date: May 6, 2002

By:



William J. Fisher
Registration No. 32,133

BANNER & WITCOFF, LTD.
1001 G Street, N.W. 11th Floor
Washington, D.C. 20001-4597
(202) 508-9100
WJF